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Alternatives to Laboratory Animals Nov 05 2020

Selected Technical Publications Aug 22 2019 Each no. represents the results of the FDA research programs for half of the fiscal year.

Supply Catalog Jun 12 2021

FDA Papers Oct 16 2021

Usp38-Nf33 Dec 18 2021

Quantitative Methods for Traditional Chinese Medicine Development Nov 17 2021 A Western-Based Approach to Analyzing TCMs In recent years, many pharmaceutical companies and clinical research organizations have been focusing on the development of traditional Chinese (herbal) medicines (TCMs) as alternatives to treating critical or life-threatening diseases and as pathways to personalized medicine. Quantitative Methods for Traditional Chinese Medicine Development is the first book entirely devoted to the design and analysis of TCM development from a Western perspective, i.e., evidence-based clinical research and development. The book provides not only a comprehensive summary of innovative quantitative methods for developing TCMs but also a useful desk reference for principal investigators involved in personalized medicine. Written by one of the world's most prominent biostatistics researchers, the book connects the pharmaceutical industry, regulatory agencies, and academia. It presents a state-of-the-art examination of the subject for: Scientists and researchers who are engaged in pharmaceutical/clinical research and development of TCMs Those in regulatory agencies who make decisions in the review and approval process of TCM regulatory submissions Biostatisticians who provide statistical support to assess clinical safety and effectiveness of TCMs and related issues regarding quality control and assurance as well as to test for consistency in the manufacturing processes for TCMs This book covers all of the statistical issues encountered at various stages of pharmaceutical/clinical development of a TCM. It explains regulatory requirements; product specifications and standards; and various statistical techniques for evaluation of TCMs, validation of diagnostic procedures, and testing consistency. It also contains an entire chapter of case studies and addresses critical issues in TCM development and FAQs from a regulatory perspective.

Pharmaceutical Dosage Forms Jul 25 2022 Pharmaceutical Dosage Forms: Parenteral Medications explores the administration of medications through other than the enteral route. First published in 1984 (as two volumes) and then last revised in 1993, this three-volume set presents the plethora of changes in the science and considerable advances in the technology associated with these products

Handbook of Stability Testing in Pharmaceutical Development Aug 14 2021 This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

The Laboratory Rabbit, Guinea Pig, Hamster, and Other Rodents May 31 2020 The Laboratory Rabbit, Guinea Pig, Hamster, and Other Rodents is a single volume, comprehensive book sanctioned by the American College of Laboratory Animal Medicine (ACLAM), covering the rabbit, guinea pig, hamster, gerbil and other rodents often used in research. This well illustrated reference includes basic biology, anatomy, physiology, behavior, infectious and noninfectious diseases, husbandry and breeding, common experimental methods, and use of the species as a research model. With many expert contributors, this will be an extremely valuable publication for biomedical researchers, laboratory animal veternarians and other professionals engaged in laboratory animal science. A new gold standard publication from the American College of Laboratory Animal Medicine series One stop resource for advancements in the humane and responsible care of: rabbit, guinea pig, hamster, gerbil, chinchilla, deer mouse, kangaroo rat, cotton rat, sand rat, and degu Includes up-to-date, common experimental methods Organized by species for easy access during bench research

Squire's Companion to the Latest Edition of the British Pharma-copoeia Oct 24 2019

Single-Use Technology Jul 13 2021 Single-Use Technology (SUT) is the first comprehensive publication of practical considerations for each stage of the implementation process of SUT, and covers the selection, specification, design and qualification of systems to meet end-user requirements. Having become readily available for all processing operations within the biopharmaceutical industry, SUT has the potential to reduce capital costs, improve plant throughput and reduce the risk of cross-contamination. However, there are no clear guidelines to aid the end-user on implementation of these technologies into a validated, good manufacturing practice (GMP) environment. This book presents approaches for the implementation within various end-user facilities and systems, SUT within regulatory frameworks (ICH Q8, Q9, Q10 and GMP), standardisation and assessment strategies, specifation of user requirements and SUT design, risk assessment and evaluation as well as qualification for different SUT types.

The National Druggist Mar 09 2021

Sample Preparation of Pharmaceutical Dosage Forms May 23 2022 This book is intended to serve as a resource for analysts in developing and troubleshooting sample preparation methods. These are critical activities in providing accurate and reliable data throughout the lifecycle of a drug product. This book is divided into four parts: Part One covers dosage form and diluent properties that impact sample preparation of pharmaceutical dosage forms

and the importance of sampling considerations in generating data representative of the drug product batch. Part Two reviews specific sample preparation techniques typically used with pharmaceutical dosage forms. Part Three discusses sample preparation method development for different types of dosage forms including addressing drug excipient interactions and post extraction considerations, as well as method validation and applying Quality by Design (QbD) principles to sample preparation methods. Part Four examines additional topics in sample preparation including automation, investigating aberrant potency results, green chemistry considerations for sample preparation and the ideal case where no sample preparation is required for sample analysis.

Biochemicals, Reagents & Kits for Life Science Research Oct 28 2022

Practical Guide to Single-use Technology May 11 2021 Single-use technology (SUT) is now available for all processing operations within the biopharmaceutical industry. It has the potential to reduce capital costs, improve plant throughput and reduce the risk of cross-contamination. However, there are no clear guidelines to aid the end-user on implementation of these technologies into a validated, good manufacturing practice (GMP) environment. This book is the first comprehensive publication of practical considerations for each stage of the implementation process of SUT, and covers the selection, specification, design and qualification of systems to meet end-user requirements.Serving as an introduction and practical reference to this growing area of application within the biopharmaceutical industry, this handbook presents:An approach for SUT implementation within an end-users facility with examples for bioreactors, tangential-flow filtration and fill-finish systems;SUT within the context of regulatory guidance, such as ICH Q8, Q9, Q10 and GMP;Strategy for standardisation of single-use bag systems and assessment of extractables and leachables;Specifications of user requirements and design of specific SUT alongside process descriptions and flow diagrams;Strategies and tools to evaluate risk with examples of risk assessments applicable to design, processing and product quality; andQualification approach for different SUT types.With the information presented in this book, engineers, researchers and professionals involved in biopharmaceuticals will be better prepared to plan and make effective decisions to design and implement SUT.

Sterilization Validation and Routine Operation Handbook (2001) Feb 20 2022 The validation and radiation sterilization process for biomaterials and medical devices requires careful planning to ensure regulatory compliance followed by precise accuracy in execution and documentation. This in-depth guide details all steps from prevalidation planning to final report and ongoing monitoring and control. Sterilization Validation & Routine Operation Handbook: Radiation provides a framework for the validation and routine operation of an irradiation sterilization process. The guidance presented complies with ANSI/AAMI/ISO 11137: 1994, Sterilization of health care product-Requirements for validation and routine control-Radiation sterilization and the newly published AAMI substantiation of 25 kGy using VDmax procedure. The author discusses methods to aid in comprehending the requirements in these standards. She also provides practical procedures for the validation and routine monitoring and control of specific gamma and electron beam radiation sterilization processes. Background chapters provide needed information on radiation sterilization technologies, sterilization microbiology, validation approaches and working with a radiation sterilization contractor. Much of the information in this new book is presented in convenient tables and charts, with diagrams and other schematics that simply illustrate appropriate validation methodologies. Sterilization Validation & Routine Operation Handbook: Radiation brings together in one resource information scattered throughout many documents and will be useful to all those involved in the sterilization of medical materials, drugs and devices.

Handbook of Toxicology Feb 26 2020 LOCATE FREQUENTLY USED INFORMATION EASILY AND QUICKLY Working in the laboratory or office, you use a diverse assortment of basic information to design, conduct, and interpret toxicology studies and to perform risk assessments. The Second Edition of the best-selling Handbook of Toxicology gives you the information you need in a single referen

Pharmaceutical Dissolution Testing Jan 19 2022 Introduction, Historical Highlights, and the Need for Dissolution Testing Theories of Dissolution Dissolution Testing Devices Automation in Dissolution Testing, by William A. Hanson and Albertha M. Paul Factors That Influence Dissolution Testing Interpretation of Dissolution Rate Data Techniques and of In Vivo Dissolution, by Umesh V. Banakar, Chetan D. Lathia, and John H. Wood Dissolution of Dosage Forms Dissolution of Modified-Release Dosage Forms Dissolution and Bioavailability Dissolution Testing and the Assessment of Bioavailability/Bioequivalence, by Santosh J. Vetticaden Dissolution Rediscovered, by John H. Wood Appendix: USP/NF Dissolution Test.

Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence Sep 27 2022 Explore the cutting-edge of dissolution testing in an authoritative, one-stop resource In Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence: Science, Applications, and Beyond, distinguished pharmaceutical advisor and consultant Dr. Umesh Banakar delivers a comprehensive and up-to-date reference covering the established and emerging roles of dissolution testing in pharmaceutical drug development. After discussing the fundamentals of the subject, the included resources go on to explore common testing practices and methods, along with their associated challenges and issues, in the drug development life cycle. Over 19 chapters and 1100 references allow practicing scientists to fully understand the role of dissolution, apart from mere quality control. Readers will discover a wide range of topics, including automation, generic and biosimilar drug development, patents, and clinical safety. This volume offers a one-stop resource for information otherwise scattered amongst several different regulatory regimes. It also includes: A thorough introduction to the fundamentals and essential applications of pharmaceutical dissolution testing Comprehensive explorations of the foundations and drug development applications of bioavailability and bioequivalence Practical discussions about solubility, dissolution, permeability, and classification systems in drug development In-depth examinations of the mechanics of dissolution, including mathematical models and simulations An elaborate assessment of biophysiologically relevant dissolution testing and IVIVCs, and their unique applications A complete understanding of the methods, requirements, and global regulatory expectations pertaining to dissolution testing of generic drug products Ideal for drug product development and formulation scientists, quality control and assurance professionals, and regulators, Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence is also the perfect resource for intellectual property assessors.

Developments in Biological Standardization Apr 10 2021

Pharmaceutical Dosage Forms - Parenteral Medications Aug 26 2022 This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the

Immunology of Insects and Other Arthropods Mar 29 2020 In insect and other arthropod immune systems, discrimination between self and nonself tissues is accomplished through the combined actions of two immunocytes and several humoral factors. Immunology of Insects and Other Arthropods presents a comprehensive look at this and other important topics in arthropod immunology. Issues discussed include insect immunocytes and other hemocytes, including computer image analysis of immunocyte serial sections; the two basic cellular immune reactions (phagocytosis and encapsulation), including the molecular basis and roles of gap junctions in encapsulation; how encapsulation is affected by polydnavirus and encapsulation-promoting factors; why insect cells are immune to HIV; humoral factors; and antibacterial factors in Lepidoptera, Diptera, and other insect orders. Other topics include hemolymph proteins interacting with mammalian complement cascade; adaptive humoral response in the American cockroach; antigenic stimulation of hemaglutinin production in insects; and the applications of the Limulus Amebocyte Lysate (LAL) in detecting endotoxins in pharmaceuticals, medical devices, clinical diagnosis, and hygienic control. This book represents an important reference source for hematologists, pathologists, immunologists, AIDS researchers, comparative immunologists, and pharmaceutical companies.

Practical Statistics for Pharmaceutical Analysis Jun 19 2019 This is an introductory statistics book designed to provide scientists with practical information needed to apply the most common statistical tests to laboratory research data. The book is designed to be practical and applicable, so only minimal information is devoted to theory or equations. Emphasis is placed on the underlying principles for effective data analysis and survey the statistical tests. It is of special value for scientists who have access to Minitab software. Examples are provides for all the statistical tests and explanation of the interpretation of

these results presented with Minitab (similar to results for any common software package). The book is specifically designed to contribute to the AAPS series on advances in the pharmaceutical sciences. It benefits professional scientists or graduate students who have not had a formal statistics class, who had bad experiences in such classes, or who just fear/don't understand statistics. Chapter 1 focuses on terminology and essential elements of statistical testing. Statistics is often complicated by synonyms and this chapter established the terms used in the book and how rudiments interact to create statistical tests. Chapter 2 discussed descriptive statistics that are used to organize and summarize sample results. Chapter 3 discussed basic assumptions of probability, characteristics of a normal distribution, alternative approaches for non-normal distributions and introduces the topic of making inferences about a larger population based on a small sample from that population. Chapter 4 discussed hypothesis testing where computer output is interpreted and decisions are made regarding statistical significance. This chapter also deasl with the determination of appropriate sample sizes. The next three chapters focus on tests that make decisions about a population base on a small subset of information. Chapter 5 looks at statistical tests that evaluate where a significant difference exists. In Chapter 6 the tests try to determine the extent and importance of relationships. In contrast to fifth chapter, Chapter 7 presents tests that evaluate the equivalence, not the difference between levels being tested. The last chapter deals with potential outlier or aberrant values and how to statistically determine if they should be removed from the sample data. Each statistical test presented includes an example problem with the resultant software output and how to interpret the results. Minimal time is spent on the mathematical calculations or theory. For those interested in the associated equations, supplemental figures are presented for each test with respective formulas. In addition, Appendix D presents the equations and proof for every output result for the various examples. Examples and results from the appropriate statistical results are displayed using Minitab 18Ò. In addition to the results, the required steps to analyze data using Minitab are presented with the examples for those having access to this software. Numerous other software packages are available, including based data analysis with Excel.

In Vitro Drug Release Testing of Special Dosage Forms Sep 22 2019 Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of: lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceutics, and regulatory affairs.

ICH Quality Guidelines Mar 21 2022 Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines Uses case studies to help readers understand and apply ICH guidelines Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)

Modern Pharmaceutics Apr 29 2020 "Completely revised and expanded throughout. Presents a comprehensive integrated, sequenced approach to drug dosage formulation, design, and evaluation. Indentifies the pharmacodynamic and physicochemical factors influencing drug action through various routes of administration."

Plastics in Medical Devices Apr 22 2022 No book has been published that gives a detailed description of all the types of plastic materials used in medical devices, the unique requirements that the materials need to comply with and the ways standard plastics can be modified to meet such needs. This book will start with an introduction to medical devices, their classification and some of the regulations (both US and global) that affect their design, production and sale. A couple of chapters will focus on all the requirements that plastics need to meet for medical device applications. The subsequent chapters describe the various types of plastic materials, their properties profiles, the advantages and disadvantages for medical device applications, the techniques by which their properties can be enhanced, and real-world examples of their use. Comparative tables will allow readers to find the right classes of materials suitable for their applications or new product development needs.

Emerging Trends in Medical Plastic Engineering and Manufacturing Jan 27 2020 Emerging Trends in Medical Plastic Engineering and Manufacturing gives engineers and materials scientists working in the field detailed insights into upcoming technologies in medical polymers. While plastic manufacturing combines the possibility of mass production and wide design variability, there are still opportunities within the plastic engineering field which have not been fully adopted in the medical industry. In addition, there are numerous additional challenges related to the development of products for this industry, such as ensuring tolerance to disinfection, biocompatibility, selecting compliant additives for processing, and more. This book enables product designers, polymer processing engineers, and manufacturing engineers to take advantage of the numerous upcoming developments in medical plastics, such as autoregulated volume-correction to achieve zero defect production or the development of intelligent single use plastic products, and methods for sterile manufacturing which reduce the need for subsequent sterilization processes. Finally, as medical devices get smaller, the book discusses the challenges posed by miniaturization for injection molders, how to respond to these challenges, and the rapidly advancing prototyping technologies. Provides a roadmap to the emerging technologies for polymers in the medical device industry, including coverage of intelligent single use products, personalized medical devices, and the integration of manufacturing steps to improve workflows Helps engineers in the biomedical and medical devices industries to navigate and anticipate the special requirements of this field with relation to biocompatibility, sterilization methods, and government regulations Presents tactics readers can use to take advantage of rapid prototyping technologies, such as 3D printing, to reduce defects in production and develop products that enable entirely new treatment possibilities

Journal of the American Pharmaceutical Association Sep 03 2020

A Text-book of Chemistry Intended for the Use of Pharmaceutical and Medical Students Jul 21 2019

Pharmaceutical Stability Testing to Support Global Markets Sep 15 2021 The International Conference of Harmonization (ICH) has worked on har- nizing the stability regulations in the US, Europe, and Japan since the early 1990s. Even though the Stability Guidelines Q1A (R2) was issued over a decade ago, issues surrounding this arena continue to surface as the principles described in the guideline are applied to different technical concentrations. As a result, the stability community has continued to discuss concerns and find ways of harmonizing regulatory requirements, streamlining practices, improving processes in order to bring safe and effective medical supplies to the patients around the world. In 2007, the American Association of Pharmaceutical Scientists (AAPS) Stability Focus Group organized two workshops the Stability Workshop and the Degradation Mechanism Workshop. These meetings attracted many industry scientists as well as representatives from several regulatory agencies in the world to discuss important topics related to pharmaceutical stability

practices. Recognizing the importance of documenting these discussions and with the permission of AAPS, I have worked with speakers to assemble a collection of 30 articles from presentations given at these two meetings, mainly the Stability Workshop. I trust that this book will be beneficial to all of you in providing guidance and up-to-date information for building quality stability programs. v Freedom of our mind is Mother of all inventions.

Industrial Sterilization Dec 26 2019

Biological Performance of Materials Jan 07 2021 Bioengineers need a thorough grounding in biocompatibility - the biological performance of materials. Until now, there were no publications suitable for a neophyte in the field; prior publications were either not comprehensive or focused on rather narrow interests. Drawing on the author's 35 years of experience as a teacher, researcher, and consult

Squire's companion to the latest edition of the British pharmacopoeia Nov 24 2019

Medical Textile Materials Jun 24 2022 Medical Textile Materials provides the latest information on technical textiles and how they have found a wide range of medical applications, from wound dressings and sutures, to implants and tissue scaffolds. This book offers a systematic review of the manufacture, properties, and applications of these technical textiles. After a brief introduction to the human body, the book gives an overview of medical textile products and the processes used to manufacture them. Subsequent chapters cover superabsorbent textiles, functional wound dressings, bandages, sutures, implants, and other important medical textile technologies. Biocompatibility testing and regulatory control are then addressed, and the book finishes with a review of research and development strategy for medical textile products. Provides systematic and comprehensive coverage of the manufacture, properties, and applications of medical textile materials Covers recent developments in medical textiles, including antimicrobial dressings, drug-releasing materials, and superabsorbent textiles Written by a highly knowledgeable author with extensive experience in industry and academia

Drug Safety Evaluation Aug 02 2020 This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics. Helps readers solve scientific, technical, and regulatory issues in preclinical safety assessment and early clinical drug development Explains scientific and philosophical bases for evaluation of specific concerns including local tissue tolerance, target organ toxicity and carcinogenicity, developmental toxicity, immunogenicity, and immunotoxicity Covers the development of new small and large molecules, generics, 505(b)(2) route NDAs, and biosimilars Revises material to reflect new drug products (small synthetic, large proteins and cells, and tissues), harmonized global and national regulations, and new technologies for safety evaluation Adds almost 20% new and thoroughly updates existing content from the last edition

The Pharmaceutical Era Dec 06 2020

Pharmaceutical Inhalation Aerosol Technology, Third Edition Feb 08 2021 This fully revised and updated third edition of Pharmaceutical Inhalation Aerosol Technology encompasses the scientific and technical foundation for the rationale, design, componentry, assembly and quality performance metrics of therapeutic inhalers in their delivery of pharmaceutical aerosols to treat symptoms or the underlying causes of disease. It focuses on the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery. The expanded scope considers previously unaddressed aspects of pharmaceutical inhalation aerosol technology and the patient interface by including aerosol delivery, lung deposition and clearance that are used as measures of effective dose delivery. Key Features: Provides a thoroughly revised and expanded reference with authoritative discussions on the physiologic,pharmacologic, metabolic, molecular, cellular and physicochemical factors, influencing the efficacy and utilization of pharmaceutical aerosols Emphasizes the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery Addresses the physics, chemistry and engineering principles while establishing disease relevance Expands the technology focus of the original volumes to address the title more directly Offers an impressive breadth of coverage as well as an international flavour from outstanding editors and contributors

Pharmaceutical Quality Control Lab Guidebook Jul 01 2020 Pharmaceutical Quality Control Lab teaches the history of regulations affecting quality control in pharmaceutical labs and their importance, and then goes into the specifics of dealing with results in a pharmaceutical lab. It contains an interactive flow chart, numerous step-by-step instructions, questions, SOP model, and a case study. It is suitable for GMP training.

Journal of Pharmaceutical Sciences Oct 04 2020 Vols. for 1912-45 include proceedings of the association's annual meeting.